



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
RESEARCH TRIANGLE PARK, NC 27711

OFFICE OF
AIR QUALITY PLANNING
AND STANDARDS

December 9, 2019

Mr. Phil Cogdill
Director of Quality Sterilization and Microbiology
Medtronic PLC
710 Medtronic Parkway
Minneapolis, MN 55432

Dear Mr. Cogdill:

Pursuant to section 114 of the Clean Air Act (CAA), the U.S. Environmental Protection Agency (EPA) is collecting information related to hazardous air pollutant emissions at ethylene oxide (EtO) commercial sterilization facilities to inform its review of the National Emissions Standards for Hazardous Air Pollutants (NESHAP) for this sector. As part of this effort, the EPA requires your assistance in providing information related to these emissions. If Medtronic PLC has previously provided information, the EPA appreciates your cooperation. However, in order to support an effective rulemaking, more information will be required.

We are requesting information regarding EtO commercial sterilization operations at the facilities specifically listed below and wholly owned by Medtronic PLC, as well as any EtO commercial sterilization facilities wholly owned by Medtronic PLC that are not included on this list:

Facility	Street Address	City	State
Covidien	195 McDermott Road	North Haven	CT
Medtronic Puerto Rico	State Road 149 Km 56.3	Villalba	PR
HeartWare	14440 Northwest 60th Avenue	Miami Lakes	FL
Xomed Surgical Products	6743 Southpoint Drive North	Jacksonville	FL
Medtronic Inc - Rice Creek	7000 Central Avenue Northeast	Fridley	MN
Medtronic PRL	11520 Yellow Pine Street Northwest	Coon Rapids	MN

The request is a survey in Microsoft® Excel format. We request that you complete and return the survey by February 6, 2020. Please download the spreadsheet and Instructions Document at: <https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions->

standards-sterilization-facilities. If there is a facility on this list not wholly owned by Medtronic PLC, please indicate that in the response letter. A completed survey is not required for that facility.

This section 114 request is designed to collect information on emissions from EtO sterilization operations, including sterilization chamber vents, aeration room vents, chamber exhaust vents, and fugitive emissions¹ at the facilities. The Instructions Document contains a summary of the instructions for completing and submitting responses to this survey request.

The survey request is designed to collect emissions information, which by law cannot be confidential business information (CBI). Submit the requested information to the EPA according to the instructions provided in Section 4 of the Instructions Document. **You are required to return all requested information to the EPA on or before the schedule due date specified in this letter.**

Supplemental information is contained in the following enclosures:

Description	Enclosure #
EPA's Information Gathering Authority Under Section 114 of the Clean Air Act	Enclosure 1
Disclosure of Emissions Data Claimed as Confidential Under Sections 110 and 114(c) of the Clean Air Act	Enclosure 2
Summary of Procedures for Safeguarding Clean Air Act Confidential Business Information	Enclosure 3
Designation of RTI International as Authorized Representative	Enclosure 4

This request is one step in an established public process for collecting foundational information as part of NESHAP reviews. The public and stakeholders will continue to have an opportunity to comment on the EtO commercial sterilization NESHAP review in the future, including a formal notice-and-comment period on any proposed action.

If you have questions regarding this survey, please contact Jonathan Witt in the EPA's Fuels and Incineration Group at 919-541-5645 or witt.jon@epa.gov.

Thank you for your assistance in this effort. The data will provide comprehensive information about the EtO commercial sterilization source category, which will lead to more effective rulemaking.

Sincerely,



Penny Lassiter
Division Director
Sector Policies and Programs Division

¹ Defined as emissions of EtO which are not routed through the existing control equipment

4 Enclosures

cc: Dennis Deziel, Regional Administrator, U.S. EPA Region 1
Peter D. Lopez, Regional Administrator, U.S. EPA Region 2
Cathy Stepp, Regional Administrator, U.S. EPA Region 5
Lynne Hamjian, U.S. EPA Region 1
John Filippelli, U.S. EPA Region 2
Ken Mitchell, U.S. EPA Region 4
John Mooney, U.S. EPA Region 5
Tracy Babbidge, Connecticut Department of Energy and Environmental Protection
Luis Sierra, Puerto Rico Department of Natural and Environmental Resources
Jeff Koerner, Florida Department of Environmental Protection
Craig McDonnell, Minnesota Pollution Control Agency
Todd Biewen, Minnesota Pollution Control Agency
Jeff Smith, Minnesota Pollution Control Agency
Frank Kohlasch, Minnesota Pollution Control Agency